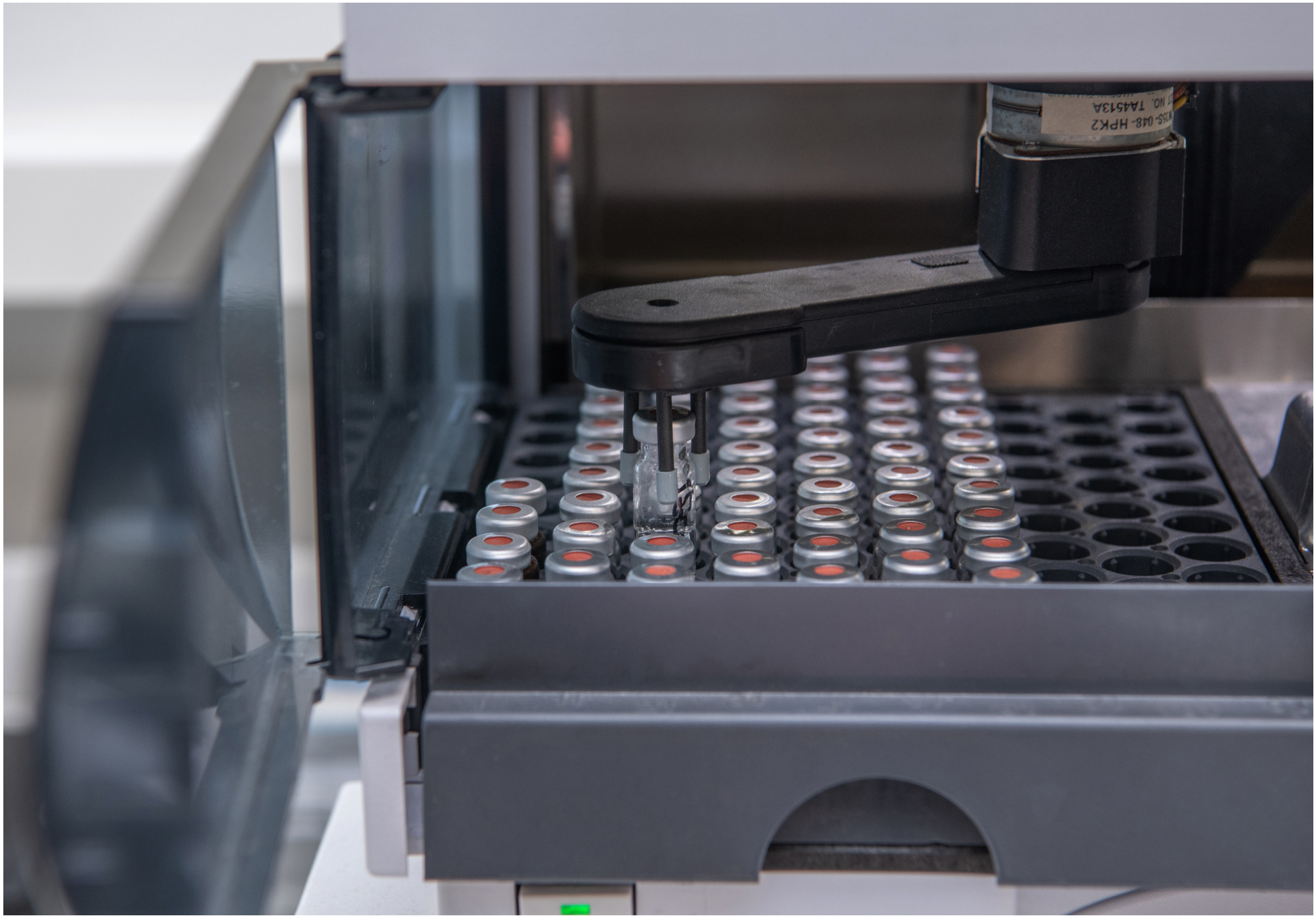
develco pharma

Where it gets difficult for others – that's where it starts for us



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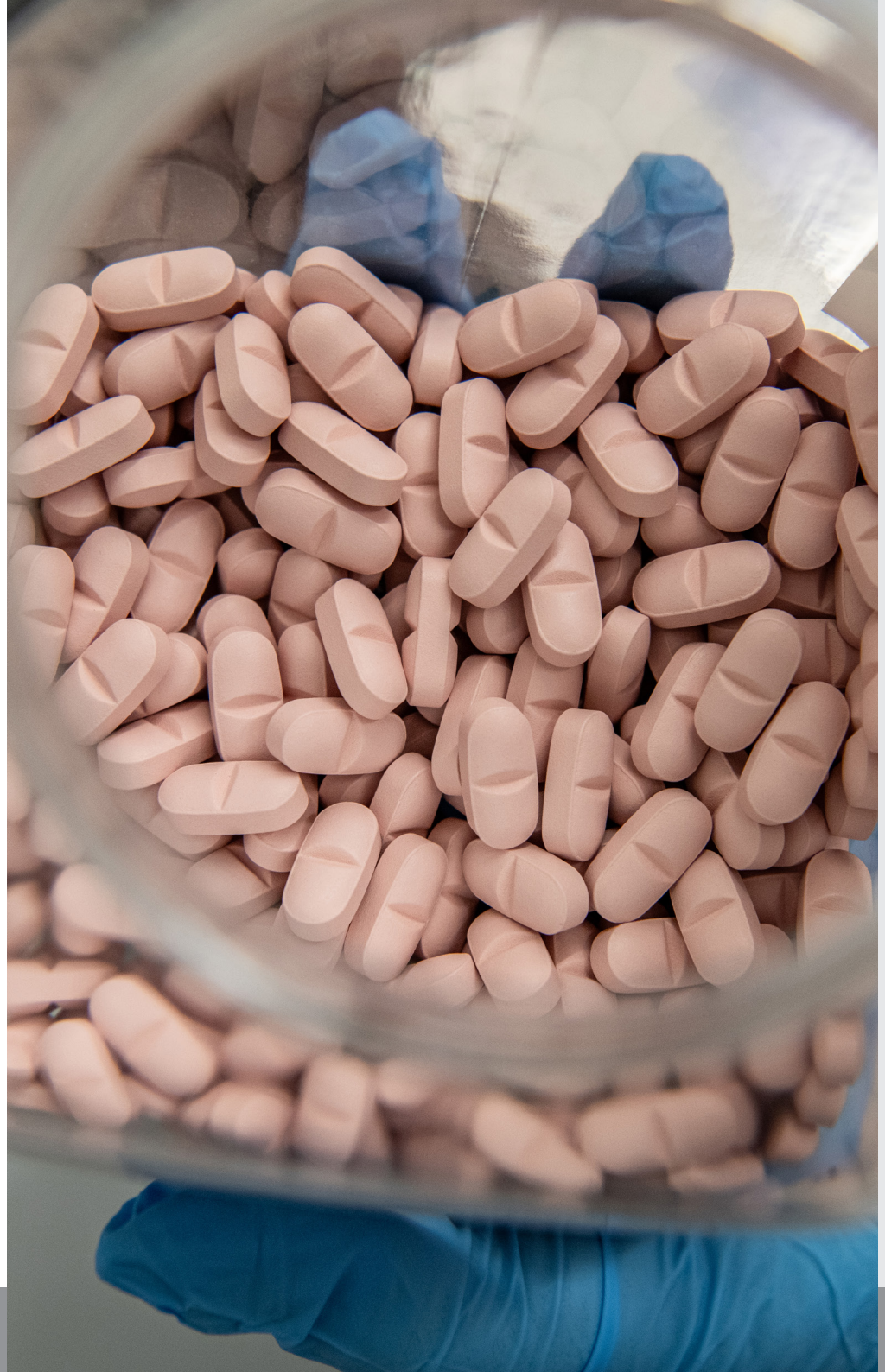


About Us

Develco Pharma is a privately owned company, located in Switzerland and southern Germany.

Our Vision: Improvement of health and quality of life of patients worldwide with the current focus on pain and ADHD.

Our Mission: Development of innovative formulations with generic APIs, targeting extended or modified release, as well as the complex manufacturing of these difficult to make drugs.

Our Strength: Innovative and creative solutions, also for complex challenges. This is true for the whole value chain, from early development, clinical design and registration up to production and supply.

Our Secret of Success: Our people. Their unique know-how meets the right positive spirit at work, so that they feel safe and part of Develco. All areas are working closely together and hand-in-hand to bring stable and efficient products to market.

Our Success Story

August 2006
Foundation of Develco Pharma Schweiz AG

January 2007
Permission to handle narcotics

October 2008
Permission to produce drugs

May 2010
First approval of a commercial product

March 2011
First Phase-III clinical study

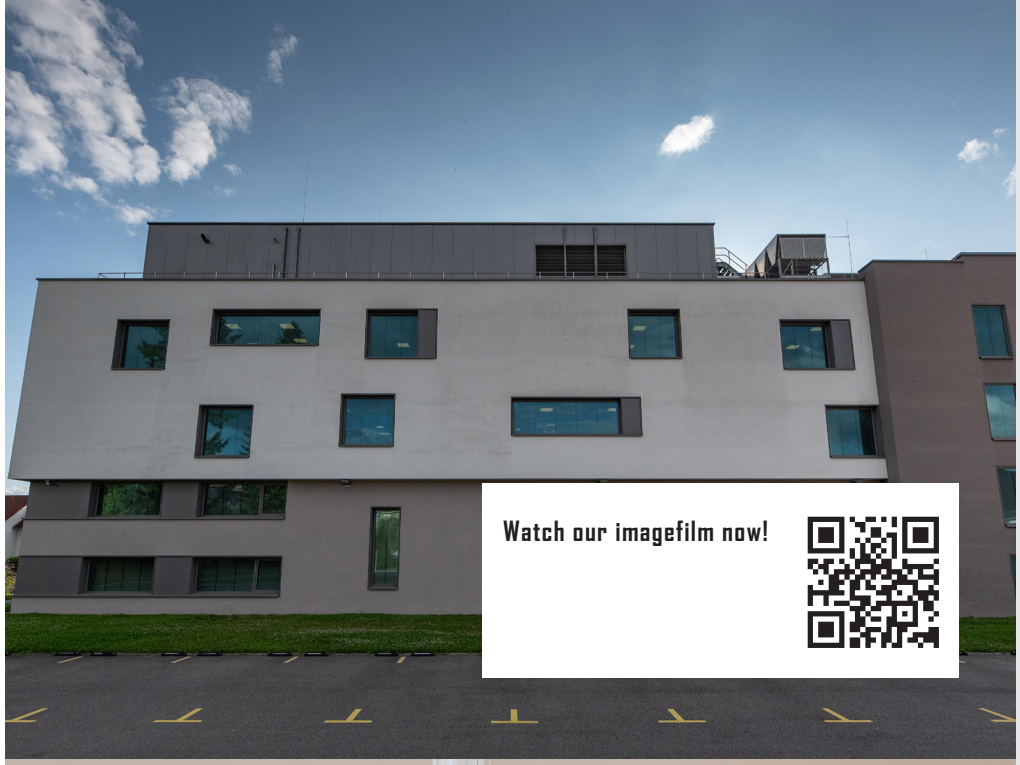
June 2013
First approval of a product in USA

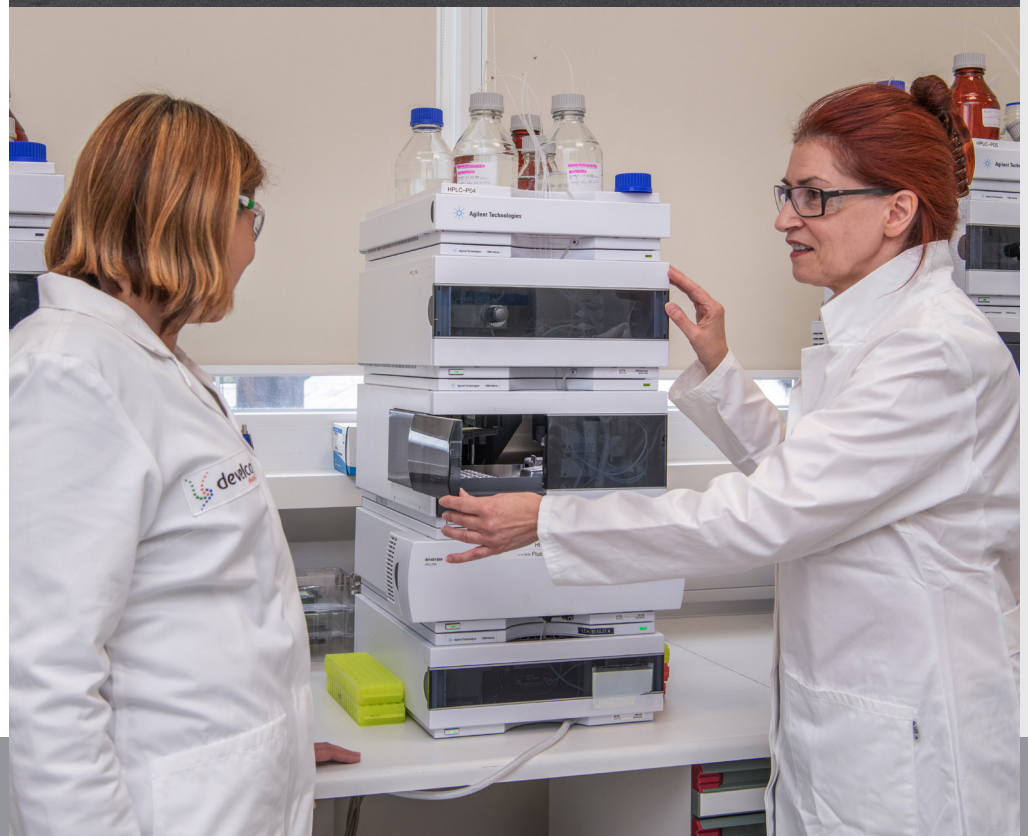
June 2015
Groundbreaking for own manufacturing site in Schopfheim, Germany

March 2018
First supply of a drug, fully produced at our own site in Schopfheim

October 2022
Inauguration and move to our new development center in Birsfelden, Switzerland

2023
More than 220 commercial approvals | more than 1 500 000 000 sold units
3 sites | 160 people | 40 licence partners





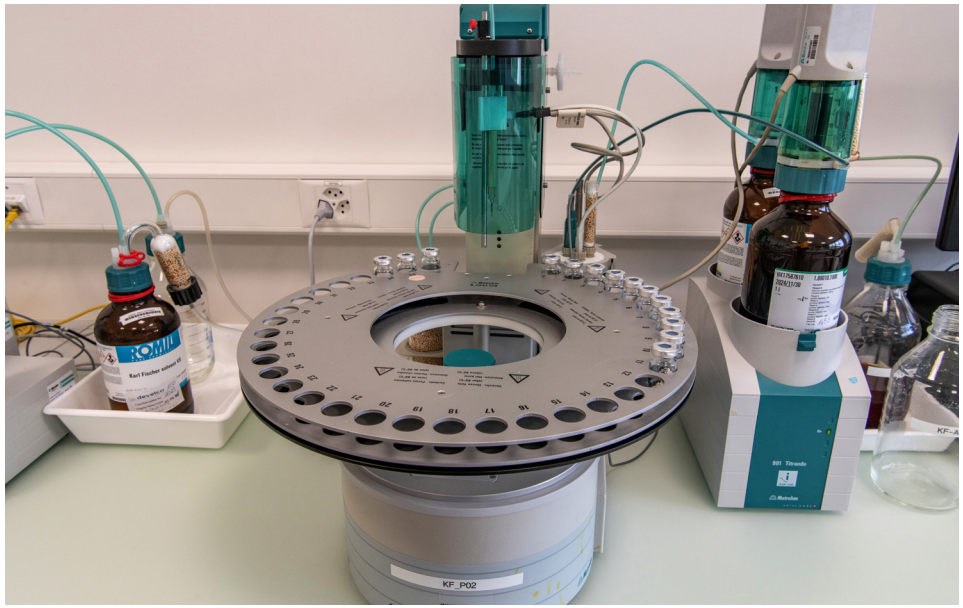
Research and Development

Formulation Development

Efficacy and safety of a drug do not only depend on the API. It is important, how it gets into the body, where and how it is released and how long it takes until it is fully absorbed. We have the know-how and experience to develop complex formulations and find the right approach, especially around tailored release of the API. In our labs and also in the closely linked pilot production, optimal formulations and processes for specialty products are jointly defined.

Analytical Development

Our analytical development labs are closely collaborating with formulation development. It is about developing GMP-suitable testing methods for the complex formulations and validating them. Short ways support direct communication and efficient collaboration – so that results on tests are available in a very short time frame. Flexible structures also enable fast decision making with all function on board at our development center in Birsfelden (CH). A prototype for trials can be developed in a very short timeframe.



Pilot Production and Manufacturing of Drugs for Clinical Trials

In our newly built, modern production site we manufacture pilot scale batches (up to 50 kg) of the formulations developed in our labs.

We then also manufacture clinical trial material there and registration batches (incl. validation). The site is set up for GMP, including later manufacturing and release for human use, also of small scale commercial material.

Reinraumsysteme & Komponenten aus eigener Fertigung.

Erstklassige **R**einraumtechnik entsteht nicht allein aus Wissen. **S**ondern aus **S**pass an der perfekten Lösung.

Reinraum-decken

Reinraum-wände

Reinraum-türen

Reinraum-leuchten

Filter-Fan-Units

Dekontaminations-duschen

Material-durchreichen

Wiege-kabinen

Unser Einsatz bei Develco

Wer wir sind.
Was wir tun.
Wofür wir stehen.

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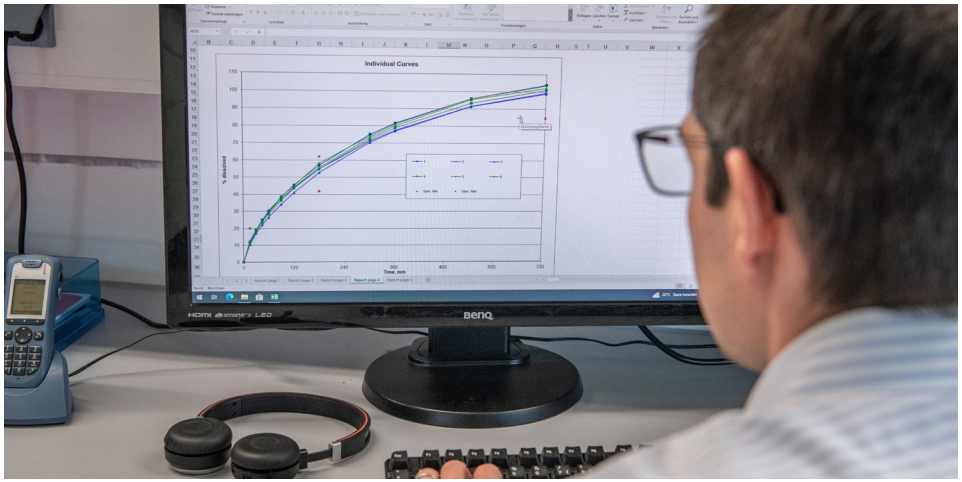
Research and Development

Management of Clinical Trials

Each new formulation and every new product are tested diligently, according to international standards. Our experienced co-workers design and supervise clinical trials (bioequivalence and Phase 2/3 trials) together with our partners. They develop the study protocol and oversee the execution according to plan and timelines. As a consequence, we can ensure the high quality and safety of our drugs for market approval.

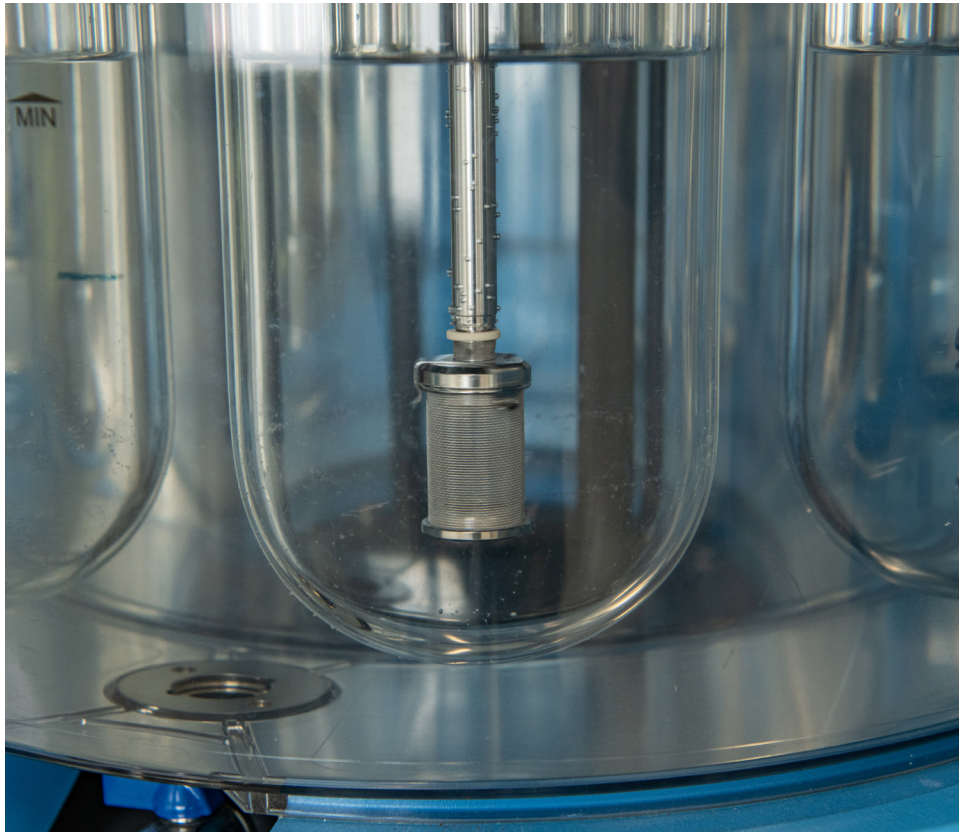
Registration Dossier

Our experts are able to create all documents for registration of the drugs. That includes development reports with descriptions of formulation, test methods and manufacturing process, development and justification of process and methods as well as results of clinical trials and product specifications.



Stability Studies

How do different temperatures of changing humidity impact the product? What influence does light have? We find out these and other aspects with physical, chemical and microbiological tests, that we develop tailor made and perform for each drug. As a result, we provide recommendations for shelf life and storage conditions.



Intellectual Property

Intellectual property plays an important role in our industry. We therefore have someone fully focused on and responsible for this topic, protecting the know-how of our company as well as verifying ideas on existing patents or the potential for new ones. As such for our products we and our customers know that we are covered legally and have an exclusivity for the products.

Production

Bulk Production

Since 2016, we produce our drugs with our modern equipment with highest standard in Schopfheim. Here we are turning into routine manufacturing, what was developed in our pilot plant. The product is highly digitalized, all rooms and production equipment is connected to our Manufacturing Execution System.

Granules, pellets, tablets and capsules are created in multiple steps in commercial scale. A specialty are very complex pellets: a solution of the API is sprayed on carrier-particles in a fluid bed granulator, followed by spraying of a polymer for modifying and ensuring a very accurate release of the API. The final pellets are then mixed with an outer phase and filled into capsules or compressed to tablets.

Final lacquering can be done for colour and shininess or for additional control of API release.

Besides manufacturing of products we have developed ourselves, we are also open for partnerships in contract manufacturing (CMO) of specialized oral solid dosage forms.


FETTE COMPACTING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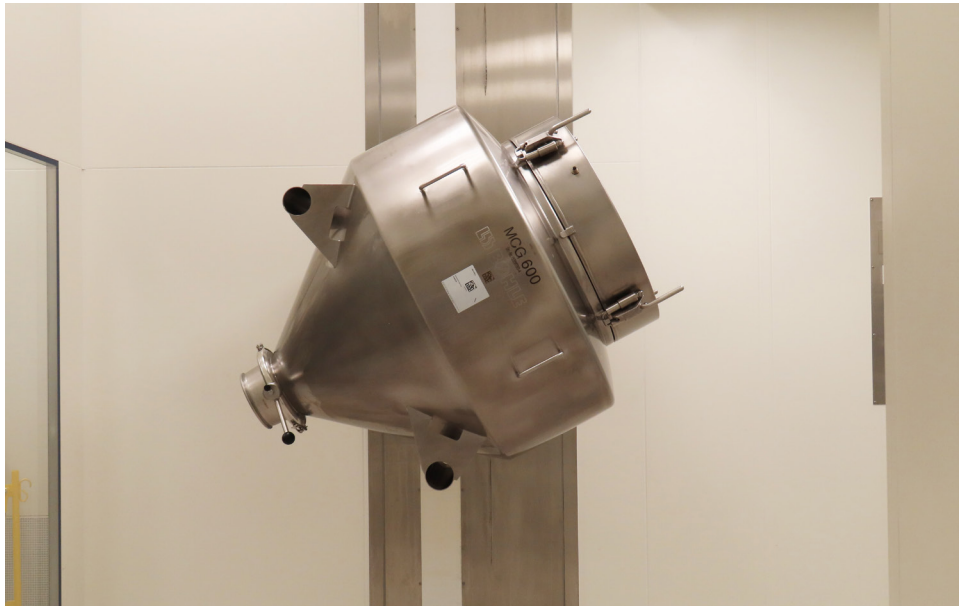
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Packaging

Packaging is done serialized on two fully automatized packaging lines.

Tablets or capsules are sealed in blisters, packed with leaflet into folding boxes, closed, bundled and packed into boxes on pallets for shipment.

We can also fill tablets and capsules into bottles and then further pack them into folding boxes automatically.

We say Thank You

Many thanks to our partners
who have contributed to realizing this brochure.

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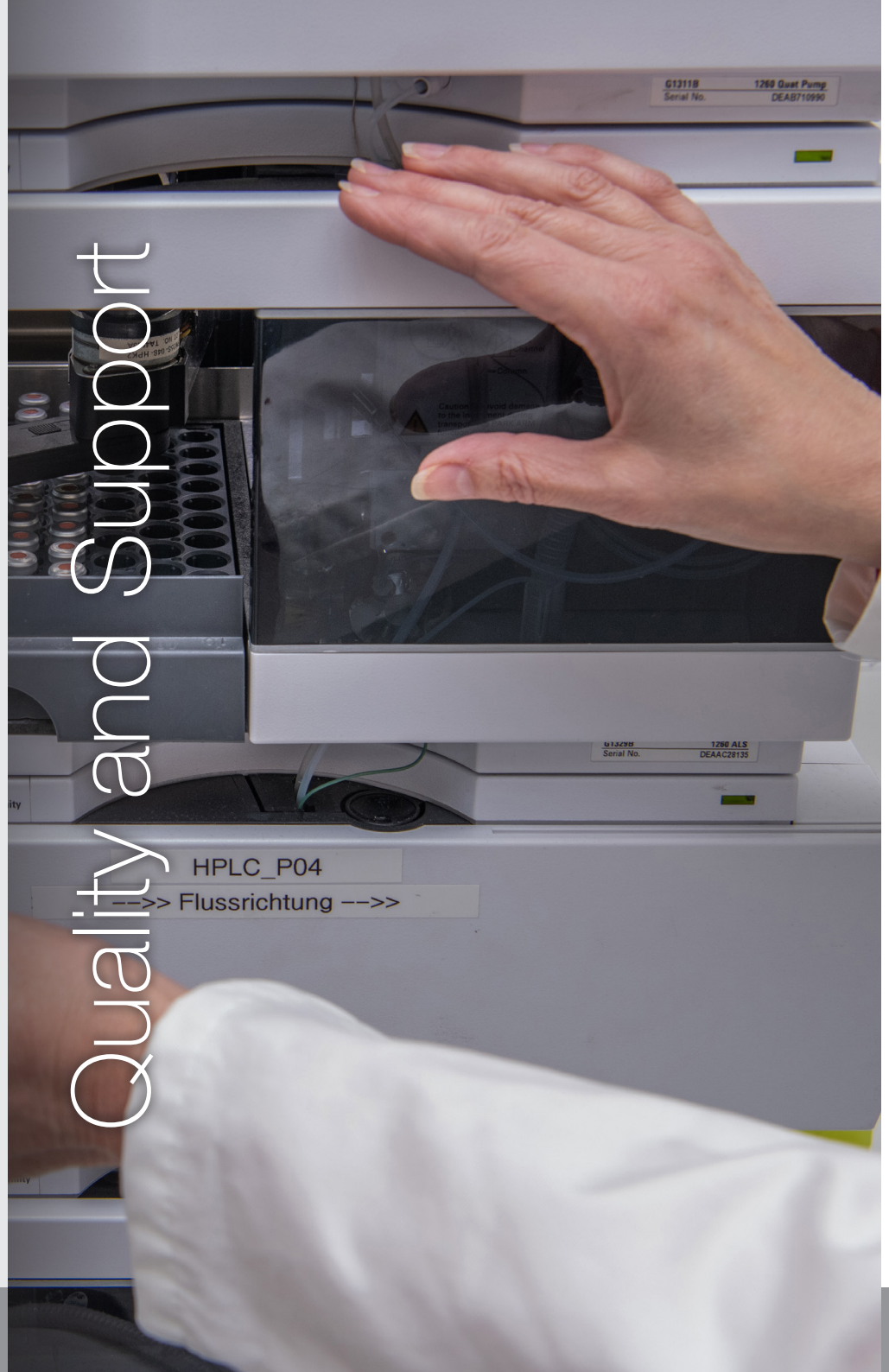

Quality and Support

Production Planning, Preparation and Storage

Planning is an important interface for purchasing, production, quality control and assurance, packaging, storage and supply to customers. Good work in this area increases efficiency and improved productivity. From product planning and bill of materials, resource planning derives the demand in raw materials, personnel and plans for preventive maintenance. Also calculation of capacities and costs of good as well as their tracking and progress of production are important.

Material stock keeping also follows the needs of production, coming from planning. Preparation of production orders, including readiness of machines and availability of material from the warehouse are executional tasks for a smooth production.

Quality Control

Our top goal is to produce special medicine in highest quality. Quality is when customers return – and not the goods. Our modernly equipped lab performs all the tests, to prove that the drugs fulfill the specifications pre-set. For our products, a key test is dissolution and release parameters. This and other tests are performed by qualified co-workers in the labs on continuously maintained and tested equipment.

Quality Assurance

Quality does not just start with production. Thus, our Quality Assurance covers nearly all formal processes in our company. That starts with training and goes way beyond any document management. Qualification of equipment, validation of methods and processes is part of it, just as risk management, internal audits and release of documents. For a better transparency and efficiency, we move forward in digitalization as much as possible, and continuously review, where we have opportunities to improve.

IT and Technical

In a more and more digitalized work environment, IT and technical team work hand in hand. The required data for all development and production processes are imported into different systems through interfaces. That way we can e.g. automatically download and print coded visualization of every pack of product in packaging. Through automation it is ensured, that connection to the machines is established, including our Digital Manufacturing Execution System. The technical team takes care of equipment, their maintenance and in case of issues their repair or replacement in line with planning, as needed.

A & O PHARMA

Wo Qualität zählt.

Sachkundige Personen nach § 14 AMG
und BTM-Verantwortliche

EU Batch Release & Consulting

- Medicinal Products
- IMPs

APPROVED

GMP-CONSULTING

- Compliance Check and Concept of QM-Systems
- Inspection-Readiness
- Inhouse-Trainings
- 3rd Party Audits and Supplier Qualification

SPECIALITIES

- GMP Consulting and Batch Release Medicinal Cannabis
- Analytical Method and Manufacturing Process transfer
- Analytical Method and Manufacturing Process transfer
- Validation of Computerrized Systems

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Licensing and Life Cycle Management

Development and Quality “Made in Europe“

Develco is established as renowned development and production company of complex oral formulations. We have more than a dozen products, that we developed, based on difficult to make technologies with focus on special properties regarding the release of the API (modified or sustained release), to ensure an API level, optimized for the drug effect.

For existing product, in case you are interested in learning more or obtaining a license for established or new markets, please reach out to us.

We also keep adding new products to our development pipeline, generic or hybrids / 505 (b) 2 products. In the course of the development process, we also like to partner, e.g. co-development. We also offer our expertise for your ideas and needs in development – as we are flexible: pragmatic, faster to the market and with attractive financial models for a joint development. We are different than pure CDMOs, as we offer a reliable solution out of one hand for your product ideas until marketing authorization, and are open to share risk and participation flexibly.

Please reach out with any idea or request.

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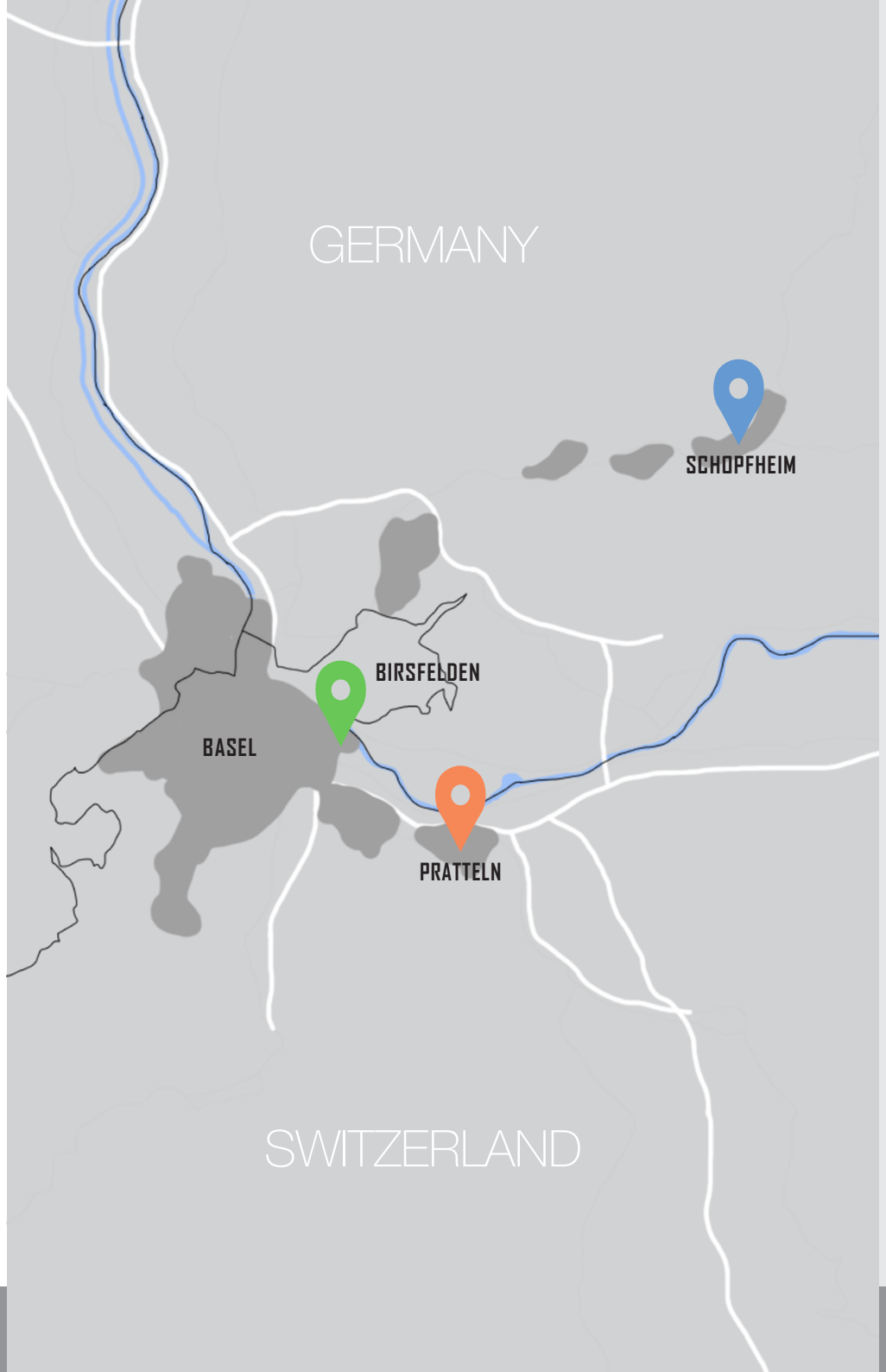

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