



Packaging means cherishing the contents





Packaging means placing your product centre stage

The Allpack Group AG was established in 2003 as a result of the merger between Allpack AG and Almedica HPS AG (formerly High Pack Services). By combining our efforts, we are now a leading service provider in the packaging and finishing segment for companies in the pharmaceutical sector. In addition to packaging pharmaceutical products, we also offer experience in the fields of health care and nutritional supplements.

We will originate and present packaging solutions to you that take into account the specific requirements of your product. That's why we dedicate care and expertise to every

enquiry. We demonstrate a wealth of ideas and creativity when it comes to development, as well as quality and perfection in fulfillment on a daily basis. We are a reliable partner and impress by virtue of our flexibility, innovation and competence.

Above-average results require extraordinary achievements. Our experienced workforce which is characterised by a high degree of commitment, experience, customer focus and professionalism, contributes vitally to this. They serve to establish the necessary mutual trust for a long-term and successful partnership with you.



Packaging means accepting no compromises in quality

In our work as a recognised packaging specialist for our customers from throughout the world, we package and finish a diversity of products for their global markets. Apart from our numerous international audits, we strive to achieve accreditation in target markets by the respective national authorities. Our production areas, plants, processes and employees translate these stringent international requirements into good manufacturing practice.

As a forward-looking, independent company with flat hierarchies and fast decision-making routes, we are able to realise developments and innovations in partnership with you in a consistent manner. In order to then achieve the highest degree of quality for you continually, duty becomes both motivation and challenge.



Packaging means unifying functionality and cost-effectiveness

We are an experienced and solution-focused partner for demanding packaging services. We are able to translate specific requirements into an economical total solution, whilst always satisfying the most stringent quality requirements. We will exploit the whole potential of innovative packaging solutions on your behalf – starting afresh with every project. We focus on values that deliver quantifiable added value for you: quality, delivery reliability, transparency and flexibility. We are the right partner to turn to for unique results.

Packaging means individual service

Our comprehensive service spectrum for individual solutions is based on

- state-of-the-art processing and production facilities at our two production sites in Reinach BL (Switzerland)
- production areas that comply with the GMP requirements of pharmaceutical companies and their specific products
- integrated processes that facilitate productive and economical packaging processes
- highly trained and motivated employees who will realise your projects in a consistent manner
- a total service package that will support your commercial success

Packaging means being at home throughout the world

We have been awarded country-specific approvals for primary and secondary packaging in the pharmaceutical industry, from

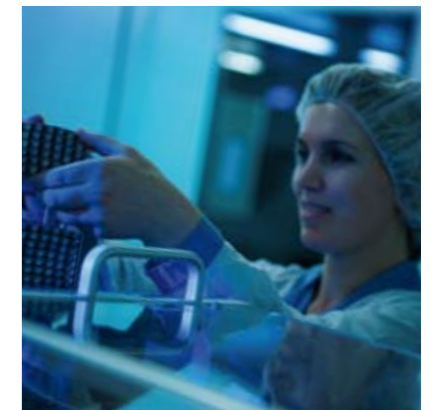
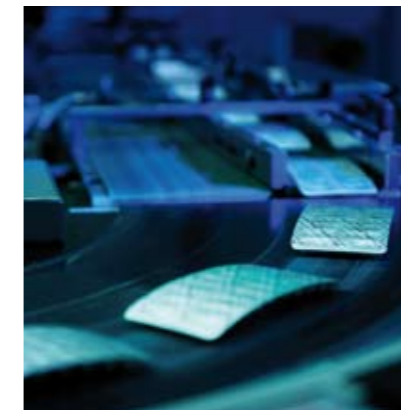
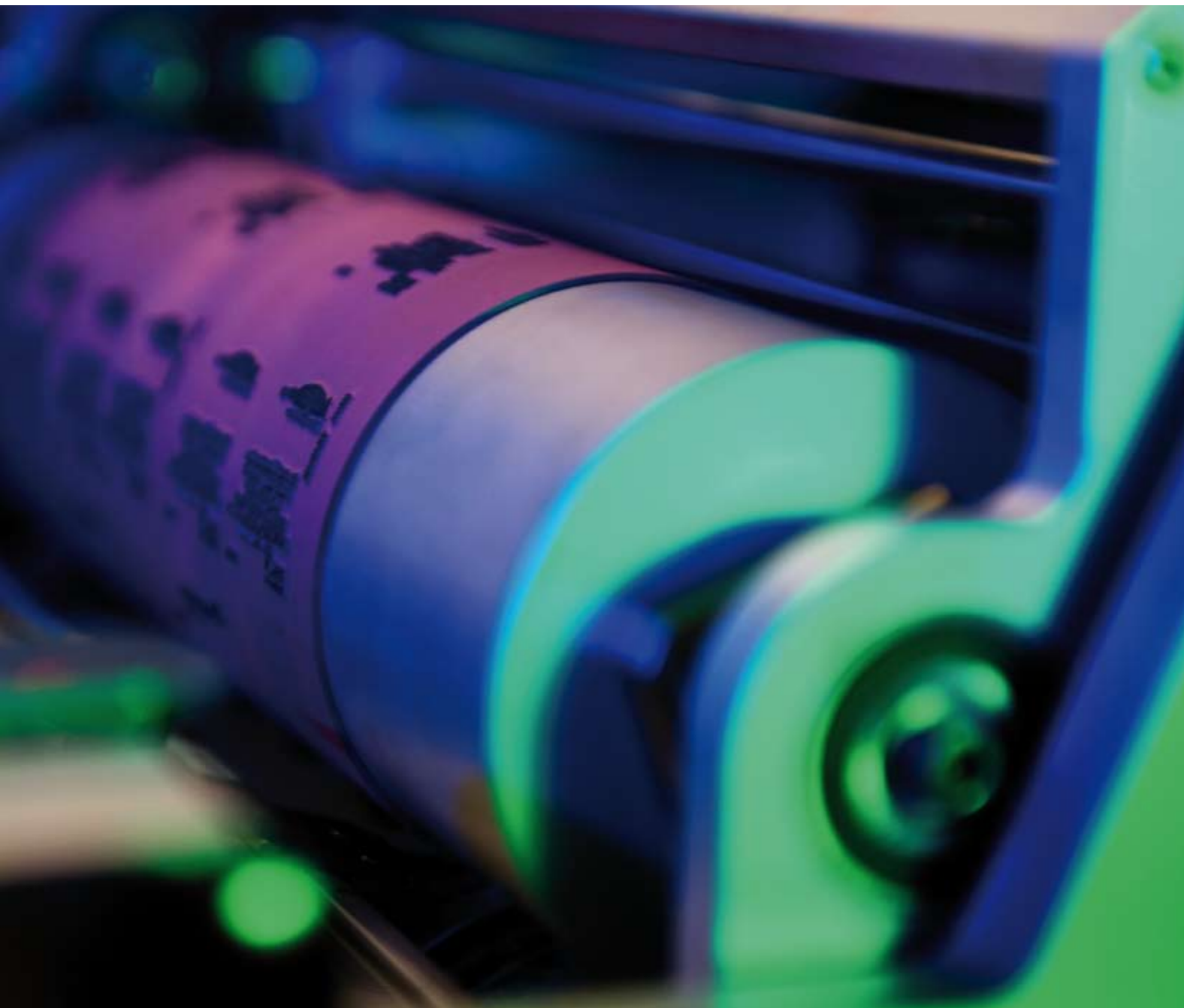
- SWISSMEDIC
- FDA (Food & Drug Administration), USA
- We have been audited by ANVISA (Brazil) as well as various pharmaceutical companies in Japan (PMDA).
- We are accredited by the Japanese Authorities (PMDA, MHLW)



Packaging means perfection from start to finish

You desire individual solutions, effectiveness and efficiency. And this is precisely what we offer you, at the highest quality and in perfection. When it comes to professional pharmaceutical packaging of the highest quality that is supplied on time, we make it our business to ensure your objectives are achieved. Your wishes set our benchmark.

Packaging means originating new designs



Our wide spectrum includes the following tailor-made solutions:

Manufacture of blister packs

We are able to blister pack a diversity of products such as capsules, tablets, dragées, ampoules, vials, injections, etc. using thermo- and cold forming processes and print the lidding foil. In addition to mono filling, we can also produce blister packs containing several products.

Filling of liquid forms

We are able to fill bottles, jars, vials etc. with liquid or semi-liquid dosage forms.

Filling bottles and jars with solid forms

We are able to fill the widest range of receptacles with capsules, tablets, dragées, powders and granulates. The bottles and jars will be produced with either screw or snap-on child-proof closures that exhibit a non-tamper guarantee (i.e. via induction sealing).

Filling sachets with solid and liquid forms

We are able to fill a wide diversity of bags such as four-side sealed bags, double-chamber bags, stand-up pouches, bottom-gusseted and contoured bags with a re-sealable closure and euroslot.

Cartoning

Be it folded boxes for various contents, package enclosures, pamphlet folding or coding the final packaging with a data matrix code. We are also able to undertake the preparatory work for printer's proofs and code reading on pharmaceutical packaging (track & trace). At Allpack, you receive everything from a single supplier.

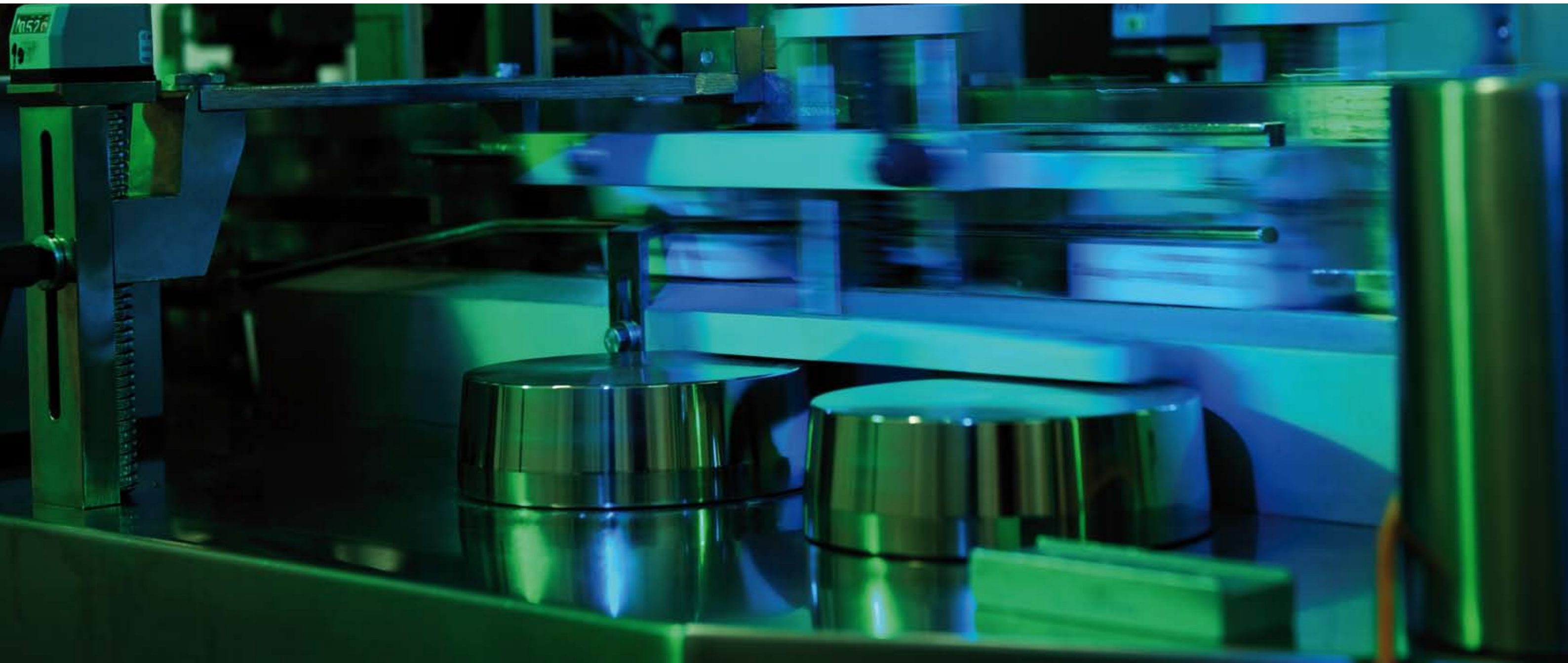
Labelling

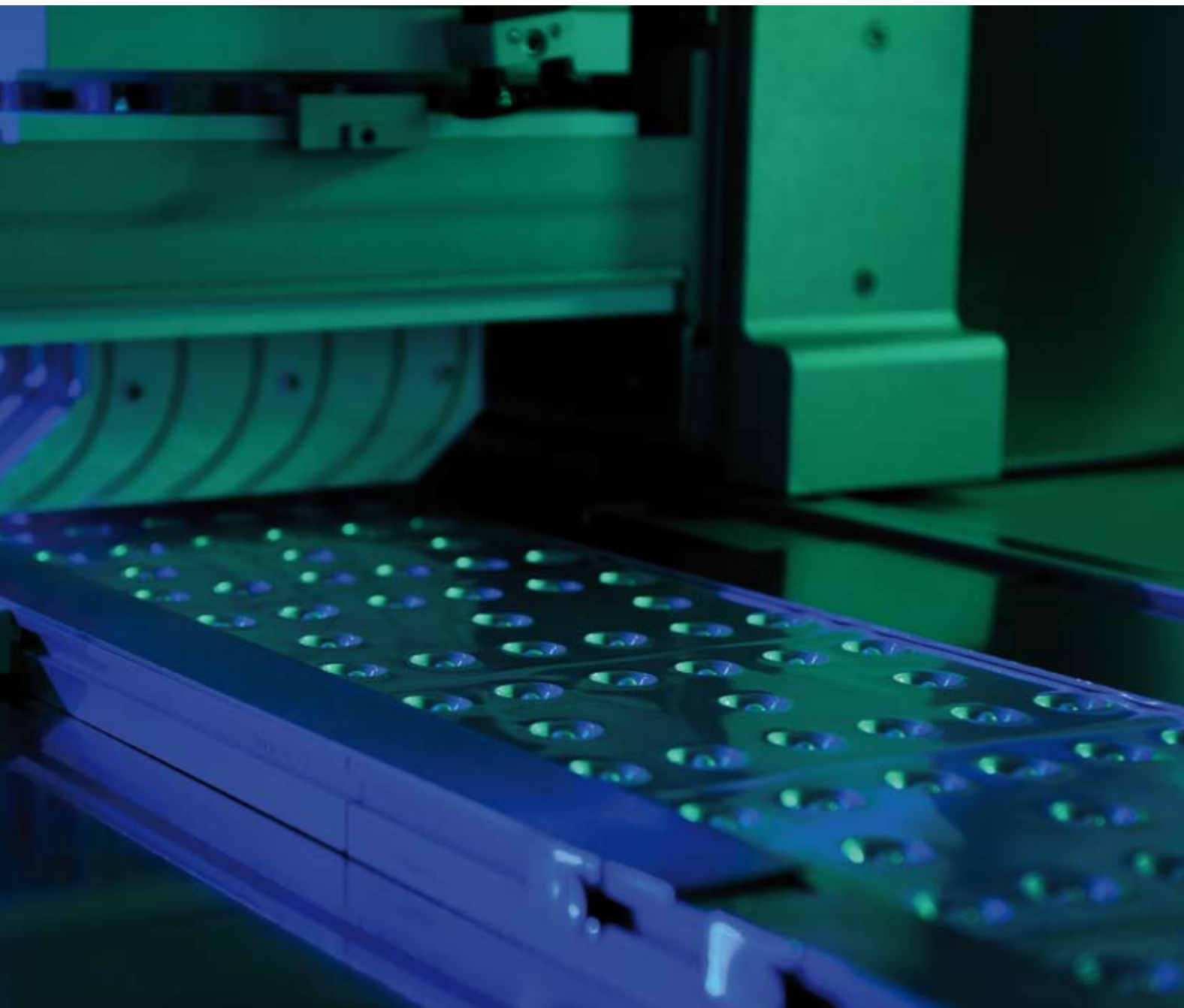
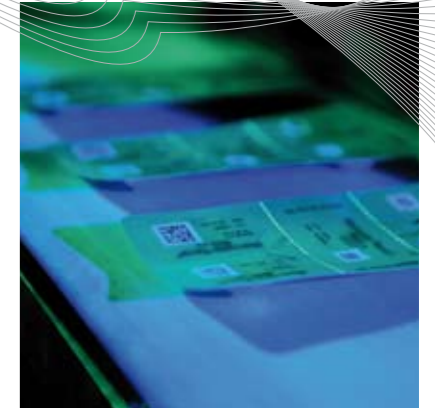
As your full-service partner, we also offer you comprehensive labelling solutions.

EU-Release

On request, we shall be pleased to guide your products through the EU-Release process in conjunction with an experienced partner.

**Packaging means delivering
tailor-made total packages**





Manual work

No quantity is too small for us. That's why we are also delighted to undertake the processing of small series, trial and stability lots, test series, repackaging orders and visual inspections.

Production areas

Our production areas are FDA and Swissmedic audited and are also compliant with PMDA standards (Japan). The packaging zones are GMP compliant (Class C and D). We guarantee the most stringent level of safety and purity, controlled temperature and humidity conditions.

Machinery and systems

Our comprehensive machinery – ranging from the packaging line through to small peripheral equipment – is continually updated and renewed to reflect the latest state of technology. Should we, however, be unable to cover your requirements with our existing packaging facilities, we remain your partner who is open to new methods and solution approaches.

Processes

Our GMP-conforming processes are streamlined, efficient, target-focused and are continually updated under the supervision of the quality assurance department. Adaptation to customer-specific requirements with respective validation is always possible. What is more, we have many years of experience with sensitive processes, for example the packaging of cooled products and productions destined for the Japanese market.

Employees

Our employees are well trained and highly motivated. The management is multilingual, with long-standing experience in the pharmaceutical sector and exemplifies flexibility, quality and a solution-focused approach in its work.

We'll find a suitable packaging solution for every phase of your product.

Entrust us with your product. We will find a solution that will enthuse you!

• **Stability samples**, which we will prepare to your precise specifications.

• **Clinical trial samples**, which we will make up in accordance with your study plan and dispatch as per your instructions (details on the clinical services pages).

• **Registration samples**, which we will also store for you and then dispatch around the world on your behalf.

• **Commercial goods**, which we can manufacture for you as per your forecast schedule, as well as on a flexible and just-in-time basis.

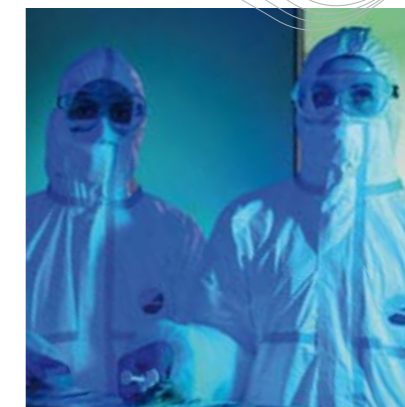


Packaging means care

No matter whether you only make use of one or our comprehensive services or take advantage of the entire spectrum, we will always tackle your projects with the same degree of care. With all of our knowledge, expertise and experience, we can concentrate fully and entirely on the tasks you have assigned us. As a competent partner, we will support you in the planning of your packaging and logistics design, as well as assist you in implementing the supply and distribution of your clinical trial samples (IMP). Thanks to our strengths when it comes to flexibility, efficiency and compliance, we can satisfy your quality, deadline and cost objectives. You, in turn, can concentrate on your key tasks and rest assured that the packaging logistics of your clinical study have been left in experts hands with us.

Packaging means perfection in fulfillment

Clinical Services



Project management

Our project managers have extensive experience that ranges from initial „first-in-human“ studies in Phase I through to large, international, multicentre studies. As your contact they will plan, coordinate and oversee your project and ensure that all the relevant information is made available at the right place and at the right time.

Procurement

We will source traditional packaging materials, tools as well as comparator drugs on your behalf. Thanks to our network of specialist partners, we are able to offer you supplementary services such as blinding by over-encapsulation and analytical tests.

Randomisation and unblinding

We are able to prepare randomisation lists for all types of study, i.e. simple or complex studies, placebo and/or competitor controlled, titration and crossover studies also employing double dummy methods. In addition, we will prepare emergency envelopes (code breakers) for the potential disclosure of individual patient medication should this prove necessary.

Identification and label printing

We will identify your trial drug, both with mono- or multilingual labels as well as booklets with any Unicode-encodable character set (including Western, Eastern European and Asian fonts). The printing and supply of labels and booklets is segregated strictly according to treatment groups, as per the specifications in the packaging plan.

Packaging

Our premises and machinery are FDA and Swissmedic audited. The validated, GMP-conforming processes are also suitable for supplies of clinical trial materials to Japan. When it comes to packaging, you can rely on our experience and expertise in primary and secondary packaging which also takes into account the special requirements that apply to clinical trial samples. What's more, we can fill blister packs with several products. We have at our disposal a large number of tools and lines for widely varying batch sizes and requirements. Our trained employees are able to package all manner of quantities and complexity levels for studies from Phase I through to Phase IV.

Quality control and EU approval

Your order-specific packaging instructions will be approved by our QA/QC department. Individual work steps will be accompanied by continual in-process checks and documented in their entirety. The order-specific packaging inspection as well as the packaged intermediate and end products will be approved in conjunction with the issue of a corresponding GMP certificate by a qualified person. On request, we shall be pleased to guide the trial drug through the EU-Release process in conjunction with an experienced partner.

Storage and distribution

We will store your clinical trial materials with access restriction within the agreed temperature ranges, and attend to the deadline-compliant worldwide distribution to study centres in conjunction with a qualified transport company. In the case of complex IVRS-supported studies, pick-label-pack order processing is also possible. We will be delighted to support you with batch tracing and the monitoring of expiry periods.

Return and disposal

We will process, account for and administer returns of clinical trial materials that have been sent back and, if requested with a qualified partner.

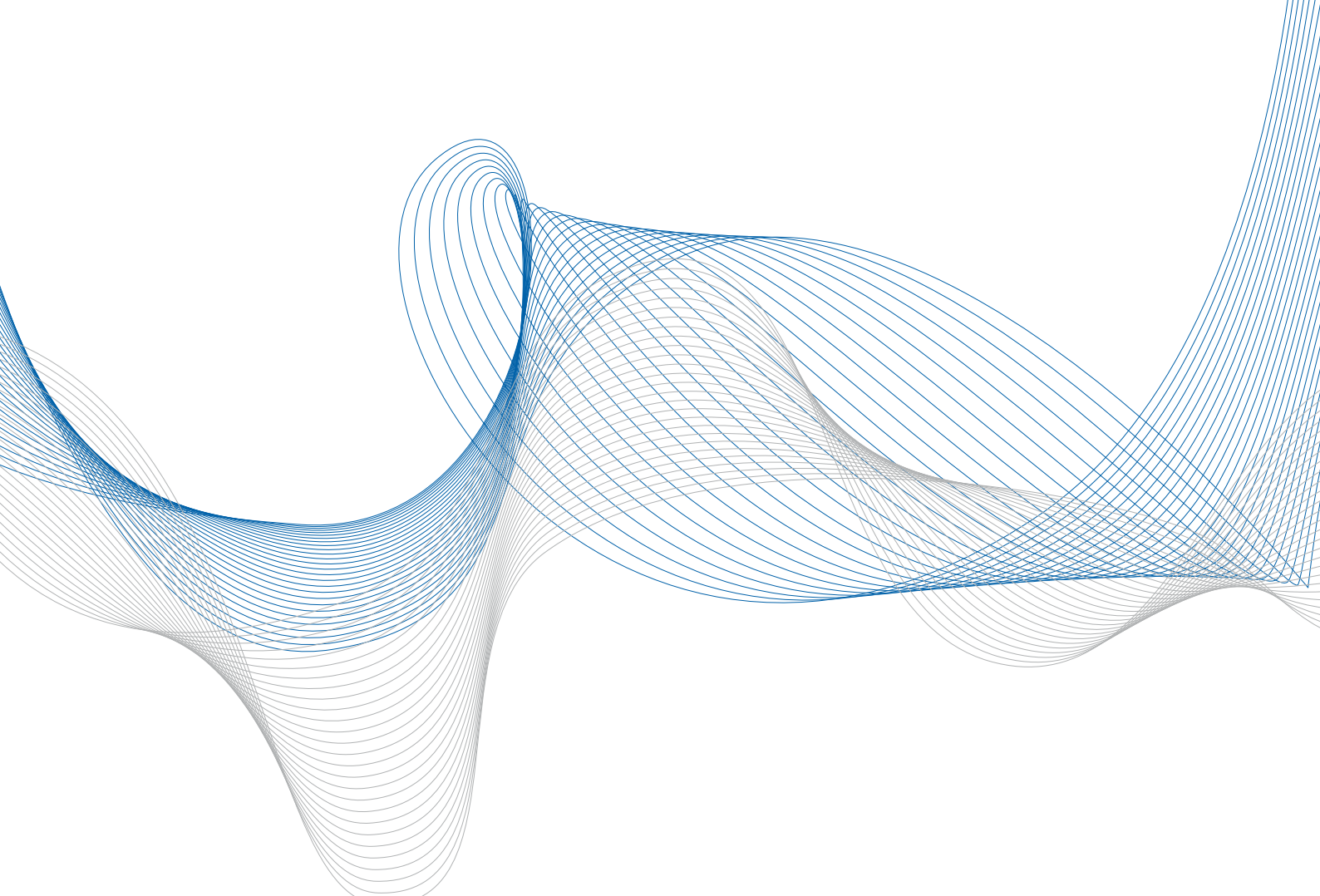
„The logistics relating to your clinical trial materials can also support you decisively in obtaining success for your new, promising pharmaceutical!“





- IMP** Investigational Medical Product (Klinisches Prüfmuster)
- GMP** Good Manufacturing Practice (Gute Herstellungspraxis)
- cGMP** Current Good Manufacturing Practice (Laufende Anpassung an die Regeln der Guten Herstellungspraxis)
- GCP** Good Clinical Practice (Regeln für die gute Durchführung von klinischen Studien)
- FDA** Food and Drug Administration (in USA: Lebensmittel- und Arzneimittelbehörde für Zulassungen)
- ANVISA** Agência Nacional de Vigilância Sanitária, Brasília
- PMDA** Pharmaceutical and Medical Devices Agency, Japan
- MHLW** Ministry of Health, Labour and Welfare, Japan
- IVRS** Interactive Voice Response System (Datenmanagementsystem für klinische Prüfungen per Telefon)

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