PRESPACK®

CONTRACT MANUFACTURING AND SERIALIZATION

Prespack – your partner in contract packaging, serialization services and aggregtion

Serialization

On 9 February 2019, regulations imposing on manufacturers the obligation to use safety features in medicinal products came into effect. Serialization not only covered the areas of assignment and printing of unique identifiers on each individual package, but also introduced the obligation to protect packaging against opening (ATD) e.g. with tamper evident labels.

In the area of serialization, Prespack offers software dedicated to managing the manufacturing process, verifying and communicating data to the central repository of serialization data (EU Hub). Among its multiple functionalities, the unique software supports the option to serialise the packaging of marketing authorisation holders (MAHs), but also marketing authorisation holders according to the parallel import procedure (PI MAHs).

SERIALIZATION

The process of serialization at Prespack consists of the following steps:

- printing and verification of unique identifiers on each individual package,
- placement of anti-tampering devices (ATD) on the packaging.

Additional serialization services:

- provision of comprehensive communication solutions for levels L1–L4,
- software for managing serialization in the production process and communicating serialization data to the EU Hub,
- possibility of integration with Connection Providers,
- serialization of non-standard unit packaging,
- serialization label for non-standard packaging, e.g. glass bottles,
- withdrawal of serial numbers – decommissioning.

Pharmaceutical aggregation

NEW

Aggregation of medicinal products is the next step after serialization. These two processes provide better control and improve the safety of medicinal products. The aggregation combines serialized unit packages of medicinal products packed in collective cartons with a higher level of collective packaging, and then with the pallet level, giving them a unique serial number. Thanks to this, it is possible to track contents of collective packaging throughout the entire supply chain.

Thanks to the implementation of pharmaceutical aggregation:

- we save time and simplify operational processes,
- we eliminate the need to open each batch or collective packaging,
- we facilitate the verification process of serialized packaging,
- we increase the efficiency of the distribution process.

Prespack implements solutions that allow you to aggregate serialization data. Thanks to this, we offer you a new service that will speed up logistics processes and definitely improve control. The new service will also enable pharmaceutical manufacturers to access CIS (Commonwealth of Independent States) markets.

AGGREGATION

DATA UPLOADING AND REPORTING

PRESPACK®

CONTRACT PACKAGING SERIALIZATION AND AGGREGATION

Prespack offers specialised services for the pharmaceutical industry in the area of contract packaging and repackaging of medicinal products into unit packages and their serialization, based on the Manufacturing or Import Authorisation for Medicinal Products, and the GMP Certificate.

Services

Prespack provides the following services for the pharmaceutical industry:

- CONTRACT PACKAGING OF MEDICINAL PRODUCTS supplied in blister packs, sachets, containers, bottles, tubes, syringes and vials – and their labelling, marking and coding in accordance with GMP principles,
- CONTRACT REPACKAGING OF MEDICINAL PRODUCTS for MAH and in the area of parallel import,
- CONTRACT SERIALIZATION as part of integrated production design, serialization data management, data communication to/from the EU Hub, as well as decommissioning of Unique Identifier,
- PHARMACEUTICAL AGGREGATION for CIS markets,
- packaging in unit packages of products containing controlled substances,
- storage of products in the so-called cold chain (+2°C to +8°C) equipped with double refrigeration system and power-loss protection system, for the purpose of further packaging or repackaging,
- production of packaging materials (Preston Packaging).

Prespack services also comprise manufacturing operations including:

- printing of batch number, expiry date and other information on blister packs, labels and single unit boxes,
- placement of labels on unit and primary packaging (e.g. non-transparent labels, Braille labels),
- preparation and packaging of promotional kits and packages,
- retention samples,
- confirmation of the manufacturing stage by Qualified Persons.

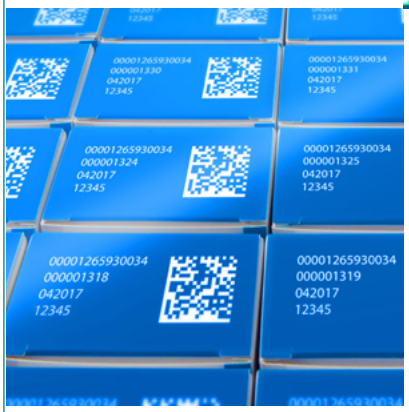
Prespack embodies four core values: commitment, quality, accuracy and attention to deadlines.

The trust of our customers motivates us to constantly improve the quality of our services.

Quality

Prespack carries out all manufacturing operations in accordance with the current GMP guidelines. Based on the Quality Assurance System implemented and constantly adjusted to current requirements, Prespack customers gain the following benefits:

- services provided on the basis of production procedures and the corporate quality policy,
- high quality of materials, repeatability and comprehensive safety of finished products,
- good communication ensuring fast supply of reliable information,
- rigorous compliance with applicable pharmaceutical hygiene standards,
- highly qualified, experienced and dedicated quality staff,
- highly qualified and trained production personnel,
- complete documentation of the manufacturing process,
- full traceability of components and products at every stage of production and storage,
- safe product storage in the so-called cold chain (at temperatures between +2°C and +8°C),
- constant improvement of qualifications of our key personnel and production staff.



PRESPACK®

CONTRACT MANUFACTURING AND SERIALIZATION

Head Office:

Prespack sp. z o.o.
34 Św. Wawrzyńca Str.
PL 60-541, Poznań
VAT no. PL7812016420

E-mail: office@prespack.pl
www.prespack.pl

Manufacturing Facility:

38 Sadowa Str.
PL 60-185, Skórzewo
Tel.: +48 61 839 24 75

FOL.EN-02-2021