PHARMACEUTICAL SERVICES …

THE MISSING PIECE OF THE PUZZLE HAS BEEN ADDED!

Drug development does not end with the development and manufacture of the galenic dosage form. This is followed by a phase of clinical trials lasting several years. A broad and highly specialized range of services is required to support the supply chain of clinical trial supplies in all phases of clinical research.

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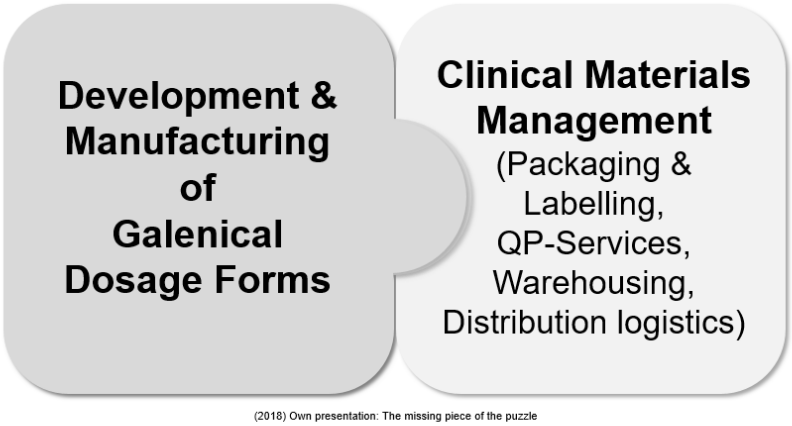

Supply Chain of Clinical Trial Materials (CTM) is now strongly supported !

Figure no. 1

SOLUTIONS TO KEEP YOU IN THE LEAD

Glatt Pharmaceutical Services (GPS) develops and produces solid pharmaceutical dosage forms. Our focus is on multiparticulate systems such as pellets, micro pellets and granules. Whether you are looking for optimal bioavailability or taste masking, improved solubility or stabilization of the dosage form, we have the right solution for every challenge.

GPS brings together fundamentals, experience and innovative technology expertise. With our comprehensive services, we support you from product idea to market launch.

For clinical studies and market supply, we manufacture medicines in bulk and efficiently bring your products to market. Our technical capabilities facilitate a seamless scale-up from the lab to commercial production scale, for which we conduct all requisite analytical studies and stability tests. For optimal processes and a secure investment.

CLINICAL SUPPLIES MANAGEMENT

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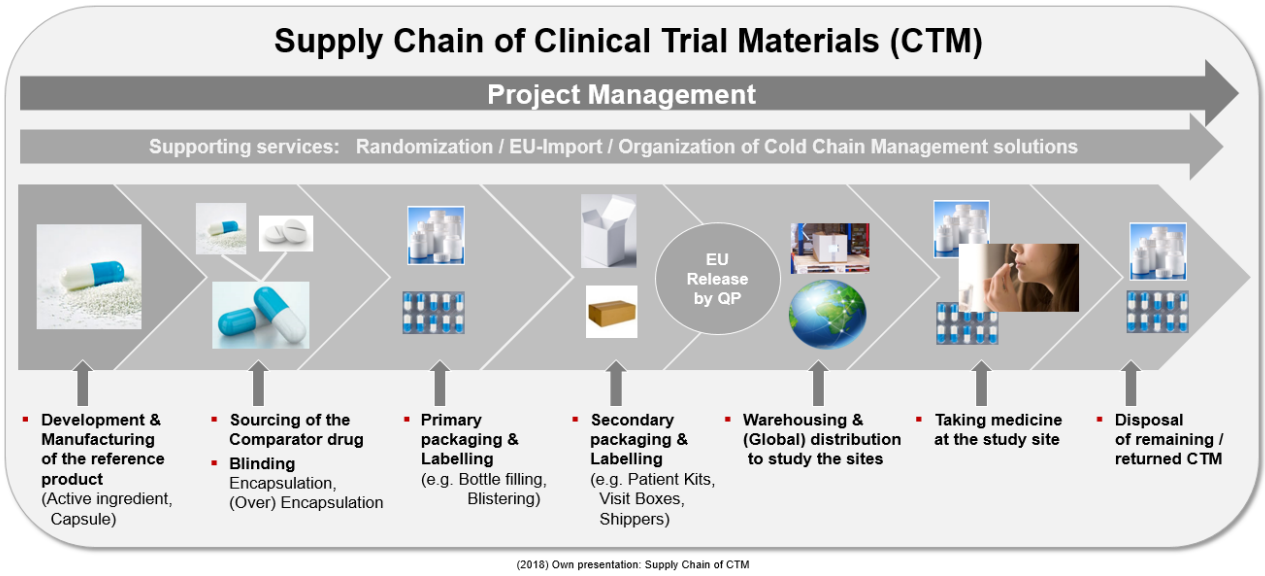

Figure no. 2

Please note that the GPS service portfolio has been significantly extended We support the complete supply chain of clinical supplies with dedicated services based on high expertise.

The well-known and proven services in the field of product development and manufacturing are now complemented by specialties like

- Sourcing of comparator drugs
- Blinding of the study medication
- Primary & Secondary packaging and labelling
- EU Release by Qualified Person (QP), incl.
  - Advice relating to regulatory requirements
  - Consultancy services regarding GMP and GDP
  - Qualification of the supply chain, audit if necessary
  - Review of the manufacturing and testing records and check of compliance with EU GMP, IMPD and with the Product Specification File
  - Release decision
  - Certificate of Analysis, Certificate of Compliance with EU GMP, IMPD and with the Product Specification File
  - Archiving of retain samples and documentation in the EU

  In addition, in case of EU-Import:

  - Definition of testing scope and release specifications for the EU
  - Incoming inspection of the received drug products, storage under quarantine until release decision
  - Sampling and batch re-analysis, if required

- Warehousing / Goods storage in appropriate areas
  - Ambient (15-25°C)
  - Cool (2-8°C)
  - Frozen (-25°C)
  - Deep frozen (-80°C)
- (Global) Distribution to the study sites; incl. organization of cold-chain-management
  - Pick, pack and shipment preparation of the clinical trials materials incl. handling of IVRS-triggers
- Drug returns
  - Organization of a certified disposal

SUPPORTING SERVICES

If you wish, we can also help you with all questions related to an EU import, customs clearance, import sales tax and use of a bonded warehouse.

PROJECT MANAGEMENT

GPS specializes in the execution of clinical development projects. An efficient project management organization forms the cross-sectional function over the entire range of clinical development and ensures that the project goals agreed with the clients are achieved.

A strong, experienced and highly motivated project management team is at the client's disposal in all matters, a "Single-Point-of-Contact" for each client is guaranteed.

The Project Management Office defines the project management standards and controls and monitors the project tasks. Manuals for all development questions and project management tasks form a solid basis for the implementation of all project-related requirements. A comprehensive quality management system (QMS) ensures compliance with GMP / GLP and GDP requirements.

Interested to get additional information? Please get in touch with us:

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Lörrach, 3rd of January, 2019 / Frieder Mayer