



- Overall consulting and project management
- Development analytics: Method development, compatibility studies, stability studies, validation etc.
- Sourcing of comparator drugs and placebos; blinding
- Finding and qualifying suitable contract manufacturing partners
- Primary and secondary packaging: bottle filling, blister packaging, walleting etc.
- IVRS / centralized patient randomization
- Label generation in all languages incl. country wise text approvals, randomization code and randomized labeling, multi-lingual and/or booklet labels
- Central warehouse in the EU (all temperature ranges), comprehensive distribution services incl. temperature-controlled transports for ambient, cold and frozen supplies
- Worldwide network of country depots, country-specific customs clearance, final distribution to the clinical sites (IVRS triggered if required)
- Handling of drug returns and certified disposal and destruction
- Legal representation of the Sponsor in the EU
- Regulatory support, including writing the PSF for the clinical trial application in EU countries

We offer the necessary services for
clinical trials in Europe
 to complete the full picture.



more than packaging

Import of Investigational Medicinal Products into the EU



Directive 2001/20/EC of the European Parliament and of the council of 4 April 2001

Manufacture and import of investigational medicinal products

... Member States shall take all appropriate measures to ensure that the qualified person referred to in Article 21 of Directive 75/319/EEC, without prejudice to his relationship with the manufacturer or importer, is responsible, in the context of the procedures referred to in Article 25 of the said Directive, for ensuring ...

... in the case of investigational medicinal products manufactured in a third country, that each production batch has been manufactured and checked in accordance with standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 91/356/EEC, in accordance with the product specification file, and that each production batch has been checked in accordance with the information notified pursuant to Article 9(2) of this Directive ...

... Member States shall take all appropriate measures to ensure that the manufacture or importation of investigational medicinal products is subject to the holding of authorisation.

Controlled transport to il-CSM's GMP warehouse, quarantine storage

Batch release and certification by il-CSM's Qualified Person, valid for all EU countries

Review of GMP and regulatory status of the supply chain, audit where necessary

Review of product specification file and batch documentation, check of compliance

Sampling and batch analysis in the EU GMP laboratory, batch record review

The missing piece of the puzzle:

Our services for Importation, Logistics and QP-Services to complete your clinical trials in the EU

1. **Qualification of the supply chain, audit if necessary**
2. **Definition of testing scope and release specifications for the EU**
3. **Review of the manufacturing and testing records and check of compliance with EU GMP and with the Product Specification File**
4. **Receipt of the IMPs in il-CSM's warehouse**
5. **Incoming inspection, storage under quarantine**
6. **Sampling and batch re-analysis**
7. **Release decision**
8. **Certification: Certificate of Analysis, Certificate of Compliance with EU GMP and with the Product Specification File**
9. **Archiving of retain samples and documentation in the EU**

il-CSM Clinical Supplies Management GmbH

is a company registered in Loerrach, in Southwestern Germany. il-CSM holds an importation license for a broad range of IMPs: from non-sterile dosage forms to sterile IMPs and vaccines, sera, test sera, and test antigens.

il-CSM has registered four Qualified Persons; each of them has many years industry experience in the Quality Assurance of IMPs.

il-CSM operates its own modern GMP warehouse where IMPs are received and stored.

il-CSM has a co-operation agreement with a GMP-certified testing laboratory located nearby, performing physicochemical and microbiological tests on behalf of il-CSM.