

CLINICAL TRIALS – DISTRIBUTION SERVICES PROVIDED IN SLOVAK MARKET. COOPERATION WITH CROs.



Zdravotnícke zásobovanie, a.s.

A company of PHOENIX group



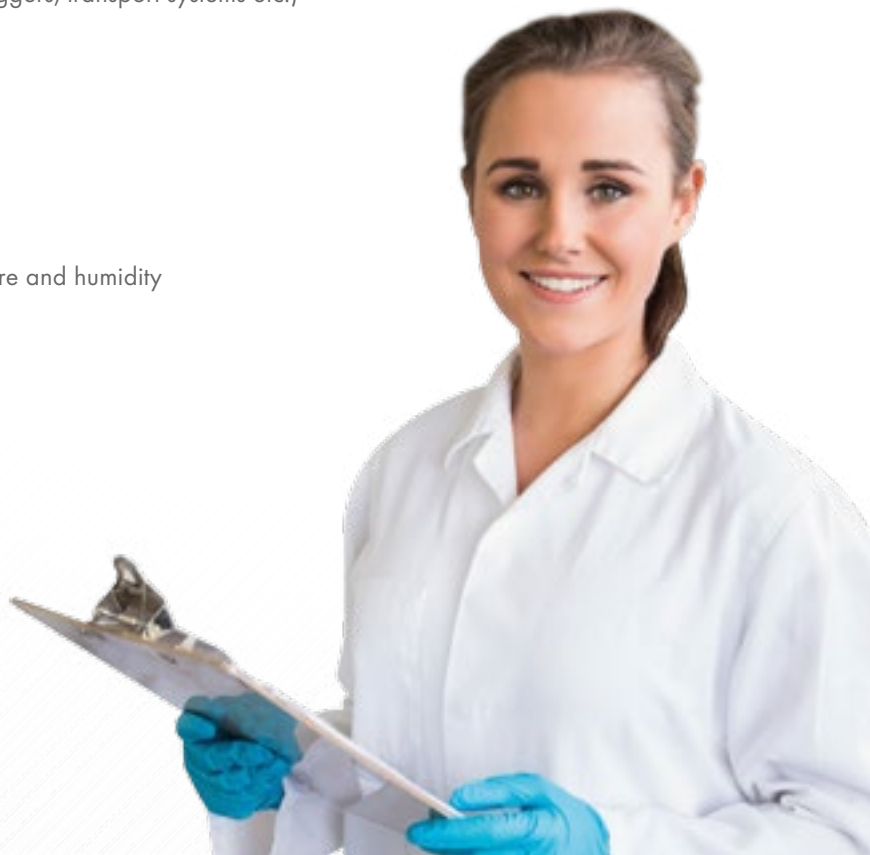
Company profile

PHOENIX Zdravotnícke zásobovanie, a. s., is a member of PHOENIX group, which is one of the biggest companies in pharmaceuticals wholesale in the European market. PHOENIX is active in 25 European countries providing its business partners with above standard services and thanks to its flexibility meeting all their needs.

One of these services is also co-operation with CROs from around the world based on the approved Statement of work

PROVIDED SERVICES IN CLINICAL TRIALS.

- Handling of import licences for narcotics
- Purchasing of products registered in Slovak republic according agreement (rescue medication etc.)
- Purchasing of related material for clinical trials (dataloggers, transport systems etc.)
- Receiving of clinical trials shipments
- Storage of clinical trials products
- Quality management
- Picking and Packing processes
- Transportation
- Validated electronical monitoring of storage temperature and humidity
- Drug returns services
- Certificated destruction of returned drugs
- Reports, KPI



IMPORT OF NARCOTICS

Arranging of import licences for narcotics used in clinical trials and communication with Ministry of Health
Evidence and archiving of documentation according to valid legislation

Receiving of clinical trials shipments

- Entrance control – first quick visual control
- Detailed entrance control according to the packing list
- Downloading of attached temperature dataloggers.
- Receive notification via e-mail and if required also notification in IXRS
- System of temperature monitoring – on line

STORAGE MODES

Temperature regime

- 15 - 25° C
- 2 - 8° C

Safety regime

- Clinical trials - standard drugs
- Clinical trials - cytostatics
- Clinical trials - narcotics

1. Separately storage
2. Separately storage + protection cover
3. Separately storage + safety box



SERVICES RELATED TO STORAGE

- separately storage space for clinical trials
- non – stop electronic system of temperature and humidity control
- alarm system after overrun temperature limits
- temperature mapping of storage space (15°C – 25°C), cooling boxes (2°C – 8°C) and trucks
- validated cold chain (receive, storage, transport)
- validation of logistic processes
- rodent control and disinsection
- sanitary regime and sanitation

RELATED SERVICES

Storage of related material – transport systems, dataloggers

Purchase of related material – upon agreement. Dataloggers, transport systems

Evidence
Reports



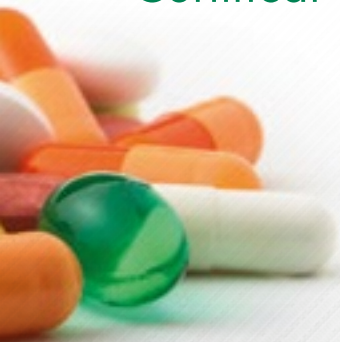
QUALITY MANAGEMENT

- systems of SOPs
- management of change control in processes
- quality risk management
- periodical trainings
- internal audits
- external audits

CERTIFICATES

Certificat of Good Distribution Practice / GDP

Certificat of Good Manufacturing Practice /GMP



PICKING AND PACKING PROCESSES

- Purchase and delivery of transport systems and dataloggers arranged by CRO
 - validated transport systems
 - calibrated temperature monitors

- Purchase of transport systems and dataloggers arranged by PHOENIX (Softboxsystems, Sofrigamsystems, TT4USB dataloggers)
 - validated transport systems
 - calibrated temperature monitors



TRANSPORT OF CLINICAL TRIALS DRUGS

Transport arranged by CRO through courier services

- Temperature monitoring arranged by courier service
- Shipping Temperature Electronic Monitoring System
- E-mail notification

Transport arranged by PHOENIX / through third party TRANSMED

TRANSMED

- contracted courier with exclusive contract with PHOENIX
- temperature monitoring arranged by PHOENIX (Comet system or upon agreement)

DRUG RETURNS QUARANTINE

- Transport of returned drugs from sites to Phoenix
- Accountability and Reconciliation
- Separately storage – quarantine regime
- Reporting

Destruction

Upon request PHOENIX arrange destruction through third party – certified company CENVIS.

Cenvis is owner of licences for destruction also for cytostatics and narcotics.

Process of destruction is supported by „Protocol of destruction“

REPORTS



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According to the agreement

- upon request
- scheduled reports upon agreement
- KPI

KPI

Quality

- % of claims from sites
- % of damaged packs within process of handling
- % inventory differences
- % of complaints (CRO, Sites, Pharmacies)

Timeframe

- evaluating of reception time
- evaluating of handling time
- evaluating of delivery time





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