SCIENTIFIC AND REGULATORY SUPPORT

at Transo-Pharm

THE CONNECTING LINK
TRANSO-PHARM

SCIENTIFIC SALES FORCE SUPPORT

- ✓ Scientific support during registration process
- ✓ Scientific evaluation of topics relating to intended administration route e.g. process water, solubility, bioburden, endotoxins, PSD

CMC DEVELOPMENT, COMPILATION AND SUBMISSION / EP & USP SUPPORT

- ✓ Holder of 8 CEP`s and US DMF`s
- ✓ Compilation of Drug Master Files (DMF), Certificates of Suitability (CEP) in eCTD (electronic Common Technical Document) including the required software
- ✓ Monograph revisions; take active part in supporting and collaborating with the EP and USP commissions
- ✓ Deficiency letter response including communication with authorities and manufacturers
- ✓ Life-Cycle management (annual reports, updates, renewals, changes)
- ✓ Document management

CUSTOMIZATION

- ✓ Transfer from development to commercialization
- ✓ Assessing initial customer requirements, specifications or product modifications

GMP / GDP

- ✓ Quality management; EU GMP certified
- ✓ Storage at our own GMP certified and climatized warehouse in Siek
- ✓ Supplier qualification program
- ✓ GMP clearance for Oceania
- ✓ CAPA and deviation management
- ✓ Batch release as per German drug law
- ✓ Training
- ✓ Contract testing at qualified laboratories

GMP & TECHNICAL SUPPORT OF MANUFACTURERS

- ✓ According to ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use), current GMP/ICH Q7 and GDP guidelines
- ✓ Due diligence
- ✓ Initial audit, QP declaration
- ✓ Initial supplier qualification
- ✓ Preparation of authority & customer audits – including mock audits and participation in authority inspections (e.g. US FDA / EDQM inspections)
- ✓ CAPA management after audits
- ✓ Technology transfer and implementation

SUPPLY CHAIN MANAGEMENT

- ✓ Transport risk evaluation / qualification of incoming and outgoing goods
- ✓ Temperature monitoring during transport if necessary or on request by customer
- ✓ Incoterms and GDP

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