

Business Readiness for new German Affiliate

Challenge



Newly founded German affiliate needed short-term business readiness

- Globally acting company (small-medium size) founded a German affiliate due to re-organization
- Affiliate needed business readiness on short term (termination of contracts for precious business solutions, own sales)
- Design of a new GDP Quality System (needed to apply for and obtain WDA*)
- Local Pharmacovigilance support and provision of the local PV-responsible
- Lean processes (limited resources)

Solution



PharmaLex extensive GDP and PV expertise and hands-on implementation support

- Gap Analyses
- Deliverables defined for GDP Quality System and PV-System
- Implementation plan, risk-based approach with definition of priorities
- Process design, SOP writing, lean processes
- Covering all interfaces between QM, PV, Reg. Affairs, Information Officer, external logistics provider
- Consultancy and support for process implementation and staff trainings
- Revision of technical agreements
- Provision of a local PV-responsible

Outcome



Achievement of business readiness in short timeframe

- Quality and local PV-systems / processes established and implemented in due time
- WDA application submitted, authority inspection successfully passed, and WDA granted by supervising authority
- Business readiness successfully reached in short timeframe
- Sales revenues generated by the affiliate

*) WDA: Wholesale Distribution Authorization