

Remediation Activities and Operational Support for local GDP Quality and PV Systems

Challenge



German affiliate of a large US company requiring maintenance support for local GDP Quality and PV Systems

- Looking for alternatives for their current cooperation with 2 freelancers for maintenance activities (one for GDP, one for PV). Wish to have one consultant for both areas
- Customer considered his GDP Quality and PV Systems up-to-date
- Limited internal staff and local know-how
- Local PV-responsible requested
- Specified operational GDP- and PV activities requested

Solution



PharmaLex as sole provider for consultancy and hands-on implementation support

- Gap analysis resulted in the need to completely remediate the existing GDP Quality System (incl. interfaces)
- Strategy and implementation plan for remediation of GDP Quality System (incl. interfaces), risk-based approach
- Process design & optimization, SOP writing
- Designing missing parts of the QMS
- Covering all interfaces to PV and customer service, logistics, Regulatory Affairs, Information Officer, EU- and global processes

Outcome



Substantial improvement of GDP Quality Systems (incl. PV interface)

- Updated and optimized processes (incl. interfaces)
- Clarified responsibilities and trained staff
- Improved management of outsourced activities
- Baseline provided for further routine maintenance of GDP and PV Systems
- Substantially improved position in view of the next authority inspections
- Support was extended to DACH* region (*Germany, Austria, Switzerland)