

# Start Up as Wholesale Distributor with business expansion plans

## Challenge



Attain business readiness of a pharma start-up as wholesale distributor on short notice

- Entrepreneur acquired several marketing authorizations for medicinal products as part of a stepwise approach to become a pharma start-up
- Excellent economic expertise, limited regulatory and technical pharma expertise
- Tough milestones in the development process: Become a wholesale distributor, switch to a new logistics partner, manage MAH-transfer
- Limited staff in the start-up phase

## Solution



PharmaLex as one-stop-shop provider for consultancy, QMS set-up and hands-on implementation support

- Strategy and implementation plan to set up a tailored GDP Quality System to obtain Wholesale Distribution Authorization
- QMS design and implementation
- Process design, SOP writing (in anticipation of future role as MAH / pharmaceutical entrepreneur), SOP- and GDP-training,
- Inspection preparation, mock inspection, active role in on-site inspection
- General consultancy

## Outcome



Achieved business readiness in short timeframe  
Established basis for future business expansion

- Implemented tailored GDP QMS
- Personnel fully trained on GDP requirements
- Reached inspection readiness within short timeframe and given excellence rating during inspection
- Obtained Wholesale Distribution Authorization & GDP certificate and quickly achieved business readiness status
- Established basis for future business expansion

Abbreviations: MAH = Marketing Authorization Holder; GDP = Good Distribution Practice; QMS = Quality Management System