

# Business Continuity during Merger

## Challenge



Maintain business continuity during merger

- Transfer of GDP-activities to a new site under jurisdiction of a new competent authority
- Application for new Wholesale Distribution Authorization and new inspection required
- QMS to be adapted and targeted to the new lean organization
- Staff fluctuation, limited human resources
- Backlogs in certain operational activities
- Tough milestones to maintain business continuity

## Solution



PharmaLex as service provider for GxP-consultancy and hands-on support at short notice

- Consultancy and hands-on support for adaptation of QMS
- Process optimization targeted to a lean organization
- Support of WDA application
- Inspection preparation and active participation in the inspection (back office)
- Staff augmentation
- Hands-on support to clear operational backlogs

## Outcome



Business readiness for new site quickly reached  
Business continuity maintained

- WDA application within shortest timeframe
- Inspection successfully passed
- Business readiness for new site rapidly reached
- Business continuity successfully maintained
- Robust basis set for subsequent changes (changes of GMP-responsibilities / activities, MAH-Transfer)

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