

# Computer Software Validation for Multinational Pharmaceutical Company

## Challenge



Pharmaceutical company acquires a European company and needs to expand in European market

- Executive management needed deployment of ERP system at the acquired European site to support the anticipated increase in business volume and complex supply chain model
- The pharmaceutical corporation needed computer software validation to meet US and EU regulatory requirements followed at other company locations
- Validation efforts necessitated remote support to work alongside implementation team

## Solution



Implement a validated ERP system to meet regulatory approval

- PharmaLex – powered by Arbour Group utilized remote consulting resources from its international testing facilities and worked with senior management and project team leaders to validate the enterprise system
- Validation deliverables included: Validation Plan, User Requirements, Product/Patient Safety Risk Assessment, Functional Specifications, Platform IQ Protocol, Application OQ Protocols, System PQ Protocol, Validation Trace Matrix, and Validation Summary Report

## Outcome



PharmaLex – powered by Arbour Group validates the software system while working with the implementation team

- This successful computer software validation project was the first validation effort for this European site
- PharmaLex – powered by Arbour Group worked with client personnel to closely train and mentor local resources throughout the project for a successful validation delivery
- European site had a validated ERP that increased reliability, reduced risk, and was ready for European market expansion